

GP 1533
#10
530-20

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

ATTORNEYS AT LAW

1100 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, D.C. 20005-3934

www.skqf.com

PHONE: (202) 371-2600 FACSIMILE: (202) 371-2540

ROBERT GREENBERG
EDWARD J. KESSLER
JORGE A. GOLDSTEIN
SAMUEL L. FOX
DAVID K.S. CORNWELL
ROBERT W. ESMOND
TRACY-GENE G. DURKIN
MICHELE A. CIMBALA
MICHAEL B. RAY
ROBERT E. SOKOHL
ERIC K. STEFFE
MICHAEL O. LEE

STEVEN R. LUDWIG
JOHN M. COVERT*
LINDA E. ALCORN
RAZ E. FLESHNER
ROBERT C. MILLONIG
MICHAEL V. MESSINGER
JUDITH U. KIM
TIMOTHY J. SHEA, JR.
DONALD R. MCPHAIL
PATRICK E. GARRETT
STEPHEN G. WHITESIDE
JEFFREY T. HELVEY*

HEIDI L. KRAUS
JEFFREY R. KURIN
RAYMOND MILLIEN
PATRICK D. O'BRIEN
LAWRENCE B. BUGAISKY
CRYSTAL D. SAYLES*
EDWARD W. YEE
ALBERT L. FERRO*
DONALD R. BANOWIT
PETER A. JACKMAN
MOLLY A. MCCALL
TERESA U. MEDLER

JEFFREY S. WEAVER
KRISTIN K. VIDOVICH
KENDRICK P. PATTERSON
DONALD J. FEATHERSTONE
GRANT E. REED
VINCENT L. CAPUANO
JOHN A. HARROUN*
MATTHEW M. CATLETT*
NATHAN K. KELLEY*
ALBERT J. FASULO II*
W. BRIAN EDGE*

KAREN R. MARKOWICZ**
SUZANNE E. ZISKA**
BRIAN J. DEL BUONO**
ANDREA J. KAMAGE**
NANCY J. LEITH**
TARJA H. NAUKKARINEN**

*BAR OTHER THAN D.C.

**REGISTERED PATENT AGENTS

May 24, 2000

WRITER'S DIRECT NUMBER:

(202) 789-5509

Commissioner for Patents
Washington, D.C. 20231

Re: U.S. Utility Patent Application
Appl. No. 09/275,883; Filed: March 25, 1999
For: **Inducible Alphaviral Gene Expression System**
Inventors: RENNER *et al.*
Our Ref: 1700.0020001/JAG/SGW

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Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction and Election of Species Requirements; and
2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Stephen G. Whiteside
Attorney for Applicants
Registration No. 42,224

Enclosures

002-1.REPLY.RR.TRANS.WPD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

RENNER *et al.*

Appl. No. 09/275,883

Filed: March 25, 1999

For: **Inducible Alphaviral Gene
Expression System**



Art Unit: 1633

Examiner: Clark, D.

Atty. Docket: 1700.0020001/JAG/SGW

**Reply To Restriction and
Election of Species Requirements**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated **April 28, 2000**, Applicants provisionally elect, *with traverse*, Group I, represented by claims 1-34, 38-70, and 74, for further prosecution. Applicants reserve the right to file one or more divisional applications directed to the non-elected inventions should the restriction requirement be made final.

Further, Applicants elect species I for initial prosecution. Applicants note that claims 1-6, 8-43 and 45-74 read on the elected species.

Remarks

Claims 1-74 are pending in the application, with claims 1, 15, 38 and 74 being the independent claims.

I. The Restriction Requirement

The Examiner has restricted the originally filed claims into the following groups:

- I.** Claims 1-34, 38-70, and 74, drawn to a DNA molecule, host cells, RNA, alphaviral particles, methods of making a cell, a protein, or a particle, methods of regulating expression of a protein by adjusting temperature, and pharmaceutical

composition comprising said DNA, classified in class 536, subclass 23.1, for instance.

- II. Claims 35-37 and 71-73, drawn to transgenic animals, classified in class 800, subclass 13, for instance.

Applicants respectfully traverse the restriction requirement as it applies to Groups I and II.

It is the Examiner's position that, "[i]nventions I and II are distinct because the inventions are directed to separate and distinct products. The invention of group I, the DNA can be used in materially processes other than making the animal of invention II. For instance, the DNA can be used to produce protein in pharmaceutical compositions as claimed." (Paper No. 9, page 2.)

Applicants respectfully disagree with the Examiner and note that even where two patentably distinct inventions appear in a single application, restriction remains improper unless the Examiner can show that the search and examination of both groups would entail a "serious burden". (*See* MPEP § 803.) In the present situation, the Examiner has failed to make such a showing.

Applicants submit that a search of the methods and compositions encompassed by claims 1-34, 38-70, and 74 would provide useful information for examination of claims directed to transgenic animals encompassed by claims 35-37 and 71-73. Thus, the searches directed to the patentability of claims which fall within Groups I and II would be overlapping.

Accordingly, the restriction requirement should be withdrawn.

In view of the above, Applicants provisionally elect, *with traverse*, Group I, represented by claims 1-34, 38-70, and 74, for further prosecution.

II. The Election of Species

The Examiner is further of the opinion that Groups I and II comprise four patentably distinct species. (Paper No. 9, page 3.) These species are as follows:

- I. Products and methods wherein the second recited ORF encodes a protein.
- II. Products and methods wherein the second recited ORF is an antisense RNA or DNA targeted to a specific nucleic acid.
- III. Products and methods wherein the second recited ORF is a ribozyme targeted to a specific nucleic acid sequence.
- IV. Products and methods wherein the second recited ORF is a tRNA or rRNA.

The Examiner has requested that Applicants elect a species for prosecution should no generic claim be finally held allowable. (Paper No. 9, page 3.) While Applicants respectfully disagree with the Examiner regarding the appropriateness of an election of species requirement, Applicants elect species I (*i.e.*, products and methods wherein the second recited ORF encodes a protein) for initial prosecution.

Applicants note that claims 1-6, 8-43 and 45-74 read on the elected species.

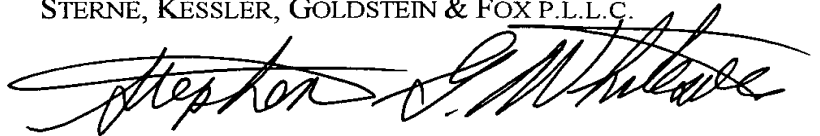
Conclusion

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

It is respectfully believed that this application is now in condition for substantive examination. Early notice to this effect is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Stephen G. Whiteside", written over a horizontal line.

Stephen G. Whiteside
Attorney for Applicants
Registration No. 42,224

Date: 5/24/00

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600